

## Michigan Department of Community Health Bureau of Laboratories

October 10, 2006

RE: Federally mandated reporting of Select Agents

Dear Colleagues:

Handling highly pathogenic organisms has always presented a challenge for clinical laboratories, however the advent of the Select Agent Rule (42 CFR 73) has increased the complexity and confusion of dealing with some organisms. The Select Agent Rule lists bacterial, viral, and fungal agents and toxins that have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. A complete list of these agents may be found at <http://www.cdc.gov/od/sap/faq.htm>.

The Centers for Disease Control and Prevention (CDC) regulates the possession, use, and transfer of select agents and toxins. The CDC Select Agent Program oversees these activities and registers all laboratories and other entities in the United States that possess, use, or transfer a select agent or toxin. Clinical laboratories that do not routinely maintain these organisms or toxins for research, testing, or quality control purposes are exempt from registration and inspection. However, this does not mean that clinical laboratories are not subject to the Select Agent Rule.

Clinical laboratories must complete and send an APHIS/CDC Form 4 (available at <http://www.selectagents.gov/FormsOverview.htm>) directly to CDC within 7 calendar days after identification of the select agent or toxin from a diagnostic specimen or within 90 days of receipt for proficiency testing containing such an agent. If a clinical laboratory forwards an isolate to a reference lab for confirmation or final identification, the report must be completed within 7 calendar days of receipt of the confirmed identification of a select agent. Under these circumstances, both the clinical laboratory and the reference laboratory must complete and submit Form 4. The laboratory that performs the definitive identification of a select agents or toxins contained in a specimen must also contact CDC (telephone: 404-718-2000, facsimile: 404-718-2096, or e-mail: [lrsat@cdc.gov](mailto:lrsat@cdc.gov)) immediately.

In addition to the reporting requirement, the identified select agent or toxin must be secured against theft, loss, or release until final disposition. Within 7 calendar days after confirmed identification of the select agent or toxin contained in a clinical specimen the agent must be transferred to a registered facility or destroyed on-site by a recognized sterilization or inactivation process. Destruction or transfer of the agent must be documented on the Form 4.

Since many select agents are highly infectious and may cause laboratory acquired infections if all appropriate safety precautions are not observed, clinical laboratories are also required to report any break in technique that may result in an occupational exposure. Clinical laboratories must notify the CDC (telephone: 404-718-2000,

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facsimile: 404-718-2096, or e-mail: [lrsat@cdc.gov](mailto:lrsat@cdc.gov)) immediately of a release ( i.e., occupational exposure or handling of an agent or toxin outside of the primary barriers of the biocontainment area suggested for the particular agent) of a select agent and toxin. The CDC must also be notified upon discovery of a theft (unauthorized removal of select agent or toxin) or loss (failure to account for select agent or toxin) of a select agent. After the initial phone report, APHIS/CDC Form 3 must be sent to the CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins. Loss or theft of, but not occupational exposure to, a select agent or toxin must also be reported to local, state, or federal law enforcement agencies. Any occupational exposure to a select agent should be reported to MDCH Kim Signs at Bureau of Epidemiology at 517-335-8165.

The implementation of the Select Agent Rule has lead to multiple revisions of the reporting requirements. If you have questions about reporting, you may contact the Select Agents program at 404-718-2000 or e-mail: [lrsat@cdc.gov](mailto:lrsat@cdc.gov) . If you isolate an organism you suspect may be *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, *Burkholderia mallei*, or *Burkholderia pseudomallei*, contact your regional confirmatory laboratory for assistance with definitive identification. If you suspect other select agents or have questions about reporting, please contact the Bureau of Laboratories at 517-335-8067. The Bureau of Epidemiology may be contacted at 517-335-8165 for consultation about occupational exposures.

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